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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/724,663 | 12/01/2003 | Michael J. Botich | 1032-P00781US4 | 2351 |
| 110 | 7590 | 03/07/2007 | EXAMINER | |
| DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307 | | | DESGANTO, MATTHEW F | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3763 | | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONTHS | 03/07/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|--------------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/724,663 | BOTICH ET AL. |
| | Examiner | Art Unit |
| | Matthew F. DeSanto | 3763 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 December 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-16 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Oath/Declaration

1. The declaration supplied 12/13/06 has been considered and the new priority date is 8/22/95 because of the continuity to application number 08/699,998, 60/002,630.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaw (USPN 5,423,758).

Shaw discloses a method for providing an injection from a medical device, comprising the steps of: providing a medical device comprising a barrel, a retractable needle, a mounting stem having a connector that is cooperable with a cartridge containing a quantity of medicinal fluid, wherein the mounting stem is spaced apart from the barrel to provide an annular passage and the device comprises an arm connected with the mounting stem and releasably engaging a recess in the barrel to retain the stem in a fixed axial position relative to the barrel

during an injection; providing a cartridge containing a quantity of medicinal fluid, comprising a fluid container and a seal comprising a connector cooperable with the connector on the stem; attaching the cartridge to the mounting stem by connecting the seal connector with the stem connector; displacing the fluid container forwardly through the annular passage until the fluid container engages the arm, whereby while the fluid container is displaced forwardly the stem maintains the seal in a fixed axial position; displacing the fluid container further forwardly after the fluid container engages the arm so that the fluid container displaces the arm, disengaging the arm from the recess and effecting release of the needle; and retracting the needle after release by means of a biasing element biasing the needle rearwardly and the apparatus (see figures 1-3 and entire reference).

3. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Jeffrey (USPN 5,487,732)

Jeffrey discloses a method and apparatus for providing an injection from a medical device, comprising the steps of: providing a medical device comprising a barrel, a retractable needle, a mounting stem having a connector that is cooperable with a cartridge containing a quantity of medicinal fluid, wherein the mounting stem is spaced apart from the barrel to provide an annular passage and the device comprises an arm connected with the mounting stem and releasably engaging a recess in the barrel to retain the stem in a fixed axial position relative to the barrel during an injection; providing a cartridge containing

a quantity of medicinal fluid, comprising a fluid container and a seal comprising a connector cooperable with the connector on the stem; attaching the cartridge to the mounting stem by connecting the seal connector with the stem connector; displacing the fluid container forwardly through the annular passage until the fluid container engages the arm, whereby while the fluid container is displaced forwardly the stem maintains the seal in a fixed axial position; displacing the fluid container further forwardly after the fluid container engages the arm so that the fluid container displaces the arm, disengaging the arm from the recess and effecting release of the needle; and retracting the needle after release by means of a biasing element biasing the needle rearwardly (Figures 2-4, and entire reference).

Response to Arguments

4. Applicant's arguments, filed 12/13/06, with respect to the priority date have been fully considered and are persuasive. The 102 Rejection of Botich et al. and 102 Rejection of Barker et al. have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Matthew DeSanto
Art Unit 3763
March 5, 2007